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EXAMINER

WEISS JR, JOSEPH FRANCIS

ART UNIT PAPER NUMBER

3761

DATE MAILED: 06/23/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/914,830

Applicant(s)
Jones et al.

Examiner
Joseph Weiss

Art Unit
3761



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 24, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on Sep 24, 2001 is/are a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 6) ☐ Other:

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DETAILED ACTION

Drawings

1. Figure 1 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

2. Claim 1 is objected to because of the following informalities: At the beginning of line 8 applicant uses the structurally connotating term "coupled" for the relationship between a trigger point of medicament delivery and its timing relative to a user's breathing cycle. A more appropriate and less structural term of "timed, targeted or correlated" is recommended. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 7-8, 15-18, 20-22, 28-30, 32, 36-37 & 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Raabe (US 5322057).

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In regards to claim 1, Raabe discloses a portable device for delivery of inhaleable medicament comprising a monitor (77/79 & 15) for monitoring a patient's breathing cycle, a medicament container (26) having a release mechanism (6) for releasing inhaleable medicament, an actuator (2, 4, 7, 11 & 82) for actuating said release mechanism, said actuator being actuable in response to a signal from said monitor, and said monitor providing said signal at a trigger point which is correlated to the end of the exhalation phase of the breathing cycle.(col. 2 line 67 to col. 3 line 2)

In regards to claim 2, Raabe discloses the use of one or more sensors for sensing the pressure profile of the breathing cycle (note sensor 15 is a pressure transducer & sensors 77/79 serve as a differential pressure transducer).

In regards to claim 3, Raabe discloses the use of one or more sensors for sensing the airflow profile of the breathing cycle (note sensors 77/79 serve as a differential pressure transducer which are used for flow monitoring).

In regards to claim 7, Raabe is fully capable of delivering medicament to a user at the point in the exhalation phase when the lungs are the most empty. (col. 2 line 67 to col. 3 line 2)

In regards to claim 8, Raabe discloses the monitor being attached to an electronic information processor (microprocessor 9).

In regards to claim 15, Raabe discloses the a display (80).

In regards to claim 16, Raabe discloses a selector (10, see push button interface of 80 that permits "selection").

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In regards to claim 17, Raabe discloses a manual selector (push buttons of 80).

In regards to claim 18, Raabe discloses the selector as operable in response to a signal from an electronic information processor. (See the supporting text of 9 & 80).

In regards to claim 20, Raabe discloses the selector having a metering mechanism (22) between the container and the release mechanism.

In regards to claim 21, Raabe discloses a multi-fire mechanism (plurality of 6s) for multiple actuation of the actuator wherein each actuation releases a portion of the optimum amount of medicament.

In regards to claim 22, Raabe discloses the use of an aerosol container (26, note containment of aerosol in its headspace) and a valve (6) as a release mechanism (note valve 6 is a valve that facilitates the generation of aerosol and hence is a "aerosol valve").

In regards to claim 28, Raabe discloses the container as being a liquid container.

In regards to claim 29, Raabe discloses an energy store for storing energy which is releasable to active the release mechanism of the medicament container. (Note the actuator's connectivity/gatekeeper role of controlling-retaining energy from line 4 & inlet 2 via 82)

In regards to claim 30, Raabe discloses the energy store aspect of the actuator comprising a biasable element (7).

In regards to claim 32, Raabe disclose the use of an energy store comprising compressed fluid (note use of pressurized gas connectable via element 2).

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In regards to claim 36, Raabe discloses a safety mechanism to prevent multiple actuations of the actuator. (See col. 5 lines 62-68)

In regards to claim 37, Raabe discloses that the end result of the safety mechanism is to impose a time delay between actuations.

In regards to claim 41, Raabe discloses a housing for containing the device. (See Fig 2).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4-6, 19, 23-24, 31, 33-35 & 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raabe.

In regards to claim 4, the reference noted above substantially disclose the claimed invention except for the use of a temperature sensor to monitor the profile, a known interchangeable equivalent with pressure sensors in the respiratory arts for performing this function.

It is noted that applicant's specification does not set forth the use of this known interchangeable equivalent, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

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Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 5, the reference noted above substantially disclose the claimed invention except for the use of moisture sensors to monitor the profile, a known interchangeable equivalent with pressure sensors in the respiratory arts for performing this function.

It is noted that applicant's specification does not set forth this known interchangeable equivalent, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

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In regards to claim 6, the reference noted above substantially disclose the claimed invention except for the use of oxygen and carbon dioxide sensors to monitor the profile, a known interchangeable equivalent with pressure sensors in the respiratory arts for performing this function.

It is noted that applicant's specification does not set forth this known interchangeable equivalent, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 19, the reference noted above substantially disclose the claimed invention to include a timer (col. 5 lines 10-25) for varying the actuation of the release means, but which is directly coupled to the release means and not the actuator as set forth by applicant, i.e. a reversal or rearrangement of known parts for a known purpose.

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It is noted that applicant's specification does not set forth this reversal of a known part for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 23, Raabe substantially discloses the instant application's invention to include a metering chamber for metering the release of medicament (head space of 26 & 31) except for the metering chamber being located in the aerosol valve, a mere reversal/rearrangement of known parts for a known purpose.

It is noted that applicant's specification does not set forth this reversal/rearrangement of known parts for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

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In regards to claim 24, Raabe discloses a metering chamber that has a variable volume. (Note that as liquid medicament is consumed, the volume the chamber (the headspace of 26) will vary).

In regards to claim 31, the reference noted above substantially disclose the claimed invention except for the use of a spring as a biasing element, a known interchangeable equivalent with solenoid biasing elements in the respiratory arts for performing this function.

It is noted that applicant's specification does not set forth the use of this known interchangeable equivalent, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patentably distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patentably distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 33, the reference noted above substantially disclose the claimed invention except for the use of voltaic cell(s) as an energy store, a known interchangeable equivalent with compressed gas pneumatic energy store in the respiratory arts for performing this function.

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It is noted that applicant's specification does not set forth the use of this known interchangeable equivalent, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 34, the reference noted above substantially disclose the claimed invention except for the use of a chemical energy source, a known interchangeable equivalent with compressed gas pneumatic energy stores in the respiratory arts for performing this function.

It is noted that applicant's specification does not set forth the use of this known interchangeable equivalent, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

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Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 35, the reference noted above substantially disclose the claimed invention except for the use of a "physically explosive energy source", a known interchangeable equivalent with compressed gas energy stores in the respiratory arts for performing this function.

It is noted that applicant's specification does not set forth the use of this known interchangeable equivalent, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of such to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to method claims 42-44, one of ordinary skill in the art would appreciate that the method steps claimed in the instant application would naturally flow from the device disclosed in the prior art as noted above and therefore are rejected herein above with respect to claims 1-41.

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7. Claims 9-14 & 38-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raabe in view of Goodman (US 5813397).

In regards to claim 9, Raabe substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of active memory to store breathing cycle data. However, Goodman disclose such (800 & supporting text regarding previous breath flow and volume maxima). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Goodman and used them with the device of Raabe. The suggestion/motivation for doing so would have been to more consistently and accurately achieve the object of the Raabe device to deliver medicament during the exhalation phase to reach the patient at the precise moment of inhalation . Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claims 10 & 11, Raabe substantially discloses the instant application's claimed invention, but does not explicitly disclose use of an algorithm or look up table to predict an optimal triggering point. However, Goodman disclose such (algorithm 800, look up table 810). The references are analogous since they are from the same field of endeavor, the

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respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Goodman and used them with the device of Raabe. The suggestion/motivation for doing so would have been to more consistently and accurately achieve the object of the Raabe device to deliver medicament during the exhalation phase to reach the patient at the precise moment of inhalation. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claims 12 & 13, the reference noted above substantially disclose the claimed invention except for the use of a second algorithm or look up table, i.e. the duplication of a known part for a known purpose.

It is noted that applicant's specification does not set forth this duplication of a known part for a known purpose, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art.

Accordingly, the examiner considers the selection of a duplication of a known part for a known purpose to be a mere obvious matter of design choice and as such does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary.

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Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 14, Raabe substantially discloses the instant application's claimed invention, but does not explicitly disclose use of a dose memory. However, Goodman disclose such (840 and supporting text). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Goodman and used them with the device of Raabe. The suggestion/motivation for doing so would have been to more consistently and accurately achieve the object of the Raabe device to deliver medicament during the exhalation phase to reach the patient at the precise moment of inhalation. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 38, Raabe substantially discloses the instant application's claimed invention, but does not explicitly disclose an actuation counter. However, Goodman disclose

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such (col. 27 line 60-67 & col. 28 lines 34 - 42). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Goodman and used them with the device of Raabe. The suggestion/motivation for doing so would have been to track dosing of a user to insure optimal treatment and amount of medicament received. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 39, Raabe substantially discloses the instant application's claimed invention, but does not explicitly disclose a dose counter. However, Goodman disclose such (col. 27 line 60-67 & col. 28 lines 34 - 42). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Goodman and used them with the device of Raabe. The suggestion/motivation for doing so would have been to track dosing of a user to insure optimal treatment and amount of medicament received. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

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Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

8. Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Raabe in view of Landis et al (US 4648393).

In regards to claim 40, Raabe substantially discloses the instant application's claimed invention, but does not explicitly disclose the use of a manual override. However, Landis disclose such (col. 3 lines 9-11). The references are analogous since they are from the same field of endeavor, the respiratory arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Landis and used them with the device of Raabe. The suggestion/motivation for doing so would have been to insure proper medicament delivery could be insured when the device malfunctions by providing for a manual override. Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention.

Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

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9. Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raabe in view of Targell (US 5310092).

In regards to claim 25, Raabe substantially discloses the instant application's claimed invention to include the chamber having a fixed volume, but does not explicitly disclose varying the metering volume by using a piston or plunger. However, Targell discloses such (see element 30). The references are analogous since they are from the same field of endeavor, the dispensing arts. At the time the instant application's invention was made, it would have been obvious to one of ordinary skill in the art to have taken the features of Targell and used them with the device of Raabe. The suggestion/motivation for doing so would have been to provide more accurately metered doses of medicament (col. 3 lines 37-40). Therefore it would have been obvious to combine the references to obtain the instant application's claimed invention. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

In regards to claim 26, the suggested device is made of a material that can "expand."

In regards to claim 27, the reference noted above substantially discloses the claimed invention except for the shape of the chamber being telescopic or concertina. It is noted that applicant's specification does not set forth this shape, as unexpectedly providing any new result or unexpectedly solving any new problem in the art over the prior art. Accordingly, the examiner considers the selection of these shapes to be a mere obvious matter of design choice and as such

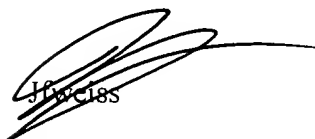
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does not patently distinguish the claims over the prior art, barring a convincing showing of evidence to the contrary. Furthermore, such a feature is old and well known in the art, and one of skill in the art would consider such to amount to a matter of mere obvious and routine choice of design, rather than constitute a patently distinct inventive step, barring a convincing showing of evidence to the contrary.

Conclusion

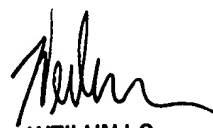
10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5826570, 5755218, 5743252, 5694919, 5522378, 5520166, 5497764, 5487378, 5479920, 5363842, 5349946, 5333106, 5284133, 5167506, 5080093, 4984158, 4829998, 4533346, 4495944

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Joseph F. Weiss, Jr., whose telephone number is (703) 305-0323. The Examiner can normally be reached from Monday-Friday from 8:30 AM to 4:30 PM. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Weilun Lo, can be reached at telephone number (703) 308-1957. The official fax number for this group is (703) 305-3590 or x3591. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0858.



JFW:c18s

June 13, 2003



WEILUN LO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700